

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-20 are pending in the application. Claims 1-19 have been amended to more particularly point and distinctly claim the present invention. Support for the changes to the claims may be found in the present specification at page 4, lines 24-27; page 5, lines 2-4; and page 5, lines 5-6.

In the outstanding Official Action, claims 1-19 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite. Applicants believe that the present amendment obviates this rejection.

The outstanding Official Action rejected claim 1 for reciting the term "a lipophilic matrix". The outstanding Official Action alleged that there was insufficient antecedent basis for this term. However, claim 1 has been amended to recite "a lipophilic matrix consisting of lipophilic compounds in which an active ingredient is at least partially incorporated". Thus, it is believed that claim 1 clearly provides antecedent basis for the term "lipophilic matrix".

Claim 4 was rejected for reciting the phrase "wherein the lipophilic matrix consists of compounds selected from the group consisting of ...". The outstanding Official Action stated

that if a matrix in claim 1 consists of C₆-C₂₀ alcohols or C₈-C₂₀ fatty acids or esters, the lipophilic matrix claimed in claim 4 may not consist of additional compounds. However, claim 4 has been amended to recite that the composition itself further comprises these compounds. As a result, it is believed that claim 4 is definite to one of ordinary skill in the art.

Claims 9 and 10 were rejected for reciting the terms "inert/amphiphilic matrix" and "lipophilic/amphiphilic matrix", respectively. However, claims 9 and 10 have been amended so that these terms are no longer recited in the claims. As a result, applicants believe that claims 9 and 10 are definite to one of ordinary skill in the art.

Claim 15 was rejected for reciting the term "lipophilic matrix". The outstanding Official Action alleged that there was no antecedent basis for this term. However, claim 15 has been amended to recite "a lipophilic matrix comprising lipophilic compounds with a melting point lower than 90°C". As a result, applicants believe that claim 15 is definite to one of ordinary skill in the art.

Thus, in view of the above, it is believed that claims 1-20 are definite to one of ordinary skill in the art.

Claims 1-20 were rejected under 35 USC §103(a) as allegedly being unpatentable over AKIYAMA et al. (EP 0514008). Claims 1-20 were then further rejected under 35 USC §103(a) as

allegedly being unpatentable over AKIYAMA et al. (U.S. Patent 6,368,635). These rejections are respectfully traversed.

Applicants respectfully submit that both AKIYAMA et al. publications fail to disclose or suggest the claimed invention.

AKIYAMA et al. describe a gastrointestinal mucosa-adherent matrix adapted to attach itself to the gastrointestinal mucosa. In particular, the matrix is designed to attach itself to a specific site of the mucosa to allow the active ingredient to act directly on the living body (page 2, lines 44-45). A viscogenic agent allows the matrix to adhere to the gastrointestinal tract and develops a sufficient degree of viscosity when in the presence of water (page 3, lines 36-38).

This stands in contrast to the present invention. In the present invention, the hydrophilic matrix forming polymer (viscogenic agent) controls the drug release rate not by promoting grafting of the composition to the intestinal mucosal wall, but by slowing the penetration of water into the composition. The present invention provides a mechanism for controlling the influx or penetration of water and/or biological fluids towards the center of the composition (page 6, lines 8-15).

Thus, in the present invention, the delivery of the active principles is controlled by slowing the dissolution rate of the matrix during its passing into the gastrointestinal tract,

and not by the muco-adhesivity of the matrix to the tract (page 10, lines 22-23).

This result is achieved through a formulation which is obtained through a dispersion of one or more active ingredients in three different matrices which are mixed together to form a homogeneous multimatrix system (page 4, line 20 to page 6, line 15; and the examples). As a result, the formulation does not contain a nucleus or similar layer. The first matrix is a lipophilic or inert matrix (page 5, line 11); the second matrix is an amphiphilic matrix (page 5, line 15) and the third matrix is a hydrophilic matrix (page 5, line 18).

As a result, the claimed invention forms a uniform matrix. This prevents the penetration of such fluids and provides a slowing down of the dissolution process without binding itself to the gastrointestinal mucosa (page 10, lines 15-30).

AKIYAMA et al. rely on a structure formed by an active ingredient coated by one or more layers forming a stratified reservoir system where only the more external layer (hydrophilic) acts binding the structure to the gastrointestinal walls allowed the release of the active ingredient.

Indeed, AKIYAMA et al. describe a composition comprising "(i) a lipid, (ii) an active ingredient and (iii) an agent having a property of becoming viscous on contact with water

and selected from..." (see claim 24) where: "A) the viscogenic agent has been dispersed at least in the neighborhood of the surface layer of a matrix particle containing the active ingredient and the polyglycerol fatty acid ester or, B) the viscogenic agent has been dispersed at least in the neighborhood of the surface layer of a matrix particle containing the active ingredient and the lipid or, C) a matrix composition such that the matrix particle has been coated with a coating composition comprising or containing the viscogenic agent" (page 3, lines 4-11).

As a result, AKIYAMA et al. describe only one matrix (the lipophilic matrix or layer containing the active ingredient and a hydrophilic compound.

Thus, in view of the above, applicants believe that both AKIYAMA et al. publications fail to anticipate the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 1-20, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

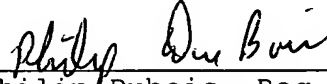
The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

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overpayment to Deposit Account No. 25-0120 for any additional
fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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